REMARKS

I. Claim Status.

Claims 1-39 are pending. Non-elected claims 15, 18, 36, 37 and 39 have been withdrawn subject to a restriction requirement. Claims 1-14, and 19-35 remain in this application. Claims 17 and 38 are canceled and new claims 40 and 41 are added. Remaining claims 1-14 and 19-45 and withdrawn claims 15, 18, 36 and 39 are amended in the present communication. No new matter is added by this amendment. Entry of this amendment is hereby requested.

II. Elections/Restrictions

Applicant affirms the election of Group I, claims 1-14, 17, 19-35 and 38, without prejudice. Applicant retains the right to pursue the non-elected claims at a future date in this or in another application. With this election, Applicant requests examination of new Claims 40 and 41, which replace canceled claims 17 and 38. In addition, Applicant requests rejoinder of the non-elected claims, where appropriate, should the elected invention be found allowable.

III. Claim Amendments.

Claims 1-14 and 19-45 are amended to clarify that the claimed invention is a "perforated tablet." Claim 1 is further amended to clarify that the pharmaceutical composition is a "mixture."

Claim 17, which depended from non-elected claim 15, is canceled and new claim 40 is added incorporating all the limitations of the canceled claim. Similarly, claim 38, which depended from non-elected claim 36, is canceled and new claim 41 is added incorporating all the limitations of the canceled claim.

Withdrawn claims 15, 18, 36 and 39 are amended in the present communication to clarify that the claimed invention is a method of making a "perforated tablet" and to place the non-elected claims in condition for rejoinder.

IV. The Rejection Under 35 USC §102.

Claims 1, 3, 4, 7, 8, 11 and 12 are rejected under 35 USC 102(b) as being anticipated by Kim US 6110500 for the reasons set forth on page six of the office action.

A claim is anticipated only if each and every element as set forth in

> the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicant respectfully traverses the rejection because the Kim reference does not describe a perforated tablet containing a pharmaceutical composition wherein "the enteric polymer is substantially hydrophobic and substantially soluble in a substantially aqueous environment above a pH of about 5" as set forth in claim 1 of the present application.

As a preliminary matter, the Kim reference does not expressly describe an "enteric polymer." However, Examiner contends that the Kim reference discloses hydroxypropylmethylcellulose and ethyl cellulose as water soluble and enteric coatings. Applicant contends that neither of these polymers are both "hydrophobic" and "substantially soluble" as set forth in Claim 1 of the present application.

Claim 1 of the Kim reference discloses a "hydrophilic, polymeric carrier" within the core of a donut-shaped tablet, which may include "hydroxypropylmethylcellulose." Moreover, the "hydroxypropylmethylcellulose" described as a "hydrophilic, polymeric carrier," in claim 1 of the Kim reference is distinguishable from the "hydroxypropylmethylcellulose acetate succinate" and "hydroxypropylmethylcellulose phthalate" enteric polymers set forth in claim 4 of the present application. It follows, therefore, that the "hydrophilic" polymer, hydroxypropylmethylcellusose, is not "hydrophobic" as set forth in claim 1.

Applicant further notes that the Patell reference (US 4775536) characterizes hydroxypropylmethylcellulose as a non-enteric polymer (see, e.g., col. 2 lines 47-65 and claim 15). Accordingly the "hydroxypropylmethylcellulose" characterized as a "hydrophilic, polymeric carrier," in claim 1 of the Kim reference is not hydrophobic, nor is it inherently an "enteric polymer."

Similarly, Claim 1 of the Kim reference discloses "a coating of hydrophobic, water-insoluble material." A set forth in Claim 3, the water-insoluble material can be ethylcellulose. Consequently, the water-insoluble ethylcellulose disclosed in the Kim reference is not "substantially soluble in a substantially aqueous environment" as set forth in Claim 1 of the present application.

The Kim reference does not expressly or inherently describe an enteric polymer in accordance with the limitations of independent claim 1. Applicant therefore requests reconsideration and withdrawal of the rejection of claim 1, as well as claims 3, 4, 7, 8, 11 and 12, which ultimately depend from claim 1.

V. The Rejection Under 35 USC § 103 .

Claims 1-6, 8-14, 17, 19-35 and 38 are rejected under USC 103(a) as being unpatentable over Patell US 4775536 in view of Marvola et al. US 5962024, for the reasons set forth on page 7 paragraph 3 to page 8 paragraph 5 of the office action.

> The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Applicant respectfully traverses this rejection because neither Patell nor Marvola et al., alone or in combination, teach or suggest Applicant's claimed invention. Moreover, the Examiner has not presented a line of reasoning factually supporting a prima facie conclusion of obviousness.

Claims 1-6, 8-14, 17, 19-35 and 38

All pending claims are limited to "a perforated tablet." Moreover, dependent claims 3 and 20 more specifically claim "the perforated tablet is a cylindrically shaped tablet, and ... the perforation extends completely through the center of the cylindrically shaped tablet." Neither Patell nor Marvola et al. teach or suggest any kind of perforated tablet. Moreover, the Examiner has not provided any suggestion of the desirability of providing the composition of Marvola et al. or the enteric coated tablet of Patell in the form of a perforated tablet. Instead, the Examiner states categorically:

> [T]he particular design of the dosage form does not provide patentable distinction over the prior art, since the composition made with multiple layers of water soluble, water insoluble, and

> enteric coatings in tablet dosage form would have the same controlled release properties without respect to shape of the tablet. (page 8, lines 7-10 of the Office Action).

Examiner's line of reasoning is not convincing (if not puzzling) for a variety of reasons. As a preliminary matter, it is not clear which "composition" the Examiner is referring to. For the sake of argument, Applicant will assume Examiner is referring to the composition of Marvola et al. Secondly, Examiner's conclusory statement provides no motivation for one of skill in the art to modify the composition of Marvola et al. (and/or Patel) from a conventional tablet shape to the perforated tablet of Applicant's claims. Finally, there is no factual support for Examiner's conclusion that the shape of the tablet has no bearing on the controlled release properties of the composition.

Indeed, the specification provides mathematical models, based on logic and sound scientific reasoning, reaching a different conclusion. For example, see equation (1) on page 15 and equation (2) on page 19 of the specification, which express the theoretical kinetic drug release rate based on the erodible surface area of the pharmaceutical composition. In both equations the dimensions of r_i, the inner radius of the hole, impact the drug release rate. Thus, the controlled release properties are not the same for perforated and conventional tablet dosage forms.

In addition, neither Patel nor Marvola et al. teach or suggest "release of the drug at a substantially constant linear rate over time, or a slightly increasing linear rate over time, or a slightly decreasing linear rate over time" as set forth in claims 7 and 24. See, *c.f.*, Fig. 1 of Marvola et al., which shows drug absorption peaking at about 4-5 hours.

Applicant further objects to Examiner's rejection of claims 17 and 38 based on the contention that no patentable distinction is imparted by the process of making a perforated tablet.

> The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) .

As set forth in new claims 40 and 41, which replace canceled claims 17 and 38, the step of "forming a perforation in the tablet" implies the presence of a structure that is not disclosed in either Patell or Marvola et al. Moreover, the process of compressing the layers, as set forth in claim 41, implies a distinctive layered structure compared to the "coated" tablet of Patell and the "enteric coating" of Marvola et al. As described above, each of these steps impact the erodible surface area and the controlled release properties of the claimed invention.

Based on the above, Applicants submit that claims 1-6, 8-14, 19-35 and 40-41 are novel and non-obvious over the cited references. Accordingly, Applicants request withdrawal of the rejections under 35 USC § 103, and allowance of all pending claims.

CONCLUSION

The Applicant believes that all pending claims are in condition for allowance and such action is earnestly requested. If the present amendments and remarks do not place the Application in condition for allowance, the Examiner is encouraged to contact the undersigned directly if there are any issues that can be resolved by telephone with the Applicants representative.

If any extension of time is required for this response, such extension is hereby requested. The Commissioner is hereby authorized to charge payment of any fees associated with this communication, if such fees are due, to Deposit Account No. 19-2090.

Respectfully Submitted,

SHELDON & MAK PC

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